

PATENT

CERVICAL PLATE/SCREW SYSTEM FOR IMMOBILIZING VERTEBRAL BODIES

Related Application

This application claims the benefit of the filing date of provisional application number 60/416,225 filed October 4, 2002 entitled PASSING THREAD LOCKING FIXATION DEVICE as to all common subject matter.

Field of the Invention

The present invention relates generally to a plate system useful, for example, to fuse segments of the human cervical spine or to stabilize an adjacent interbody device from the anterior aspect. More specifically the invention relates to a device used to align and maintain the alignment between adjacent vertebrae and interbody device where applicable in a predetermined spatial relationship by a qualified surgeon during spinal fusion.

Background of the Invention

Current practice in the art of cervical spinal fusion is to use a cervical plate which secures adjacent vertebrae. These systems typically use multiple screws which attach the vertebrae body and occasionally bone graft to the plate. The surgeon decides upon the spatial orientation through manipulations, and then affixes the securing plate. Plates are generally designed to place 2 screws into each vertebra body. Some plates allow the screw(s) to be placed in only one or in up to a maximum of four unique locations per body. The screws are prevented from "backing out" or becoming removed from the plate by various locking or blocking means. Plate and screw combinations allow for screws to be placed at a fixed or variable angle relative to the plate. A few plates allow for a dynamic settling of the vertebrae bodies by allowing screws positioned in adjacent vertebra bodies to approach. This is accomplished by either allowing the screws to slide within the

1 plate or by allowing the plate to compress in a telescopic manner.

2 Summary of the Invention

3 It is an object of the invention to provide a plate system, i.e., plate, and screw combination
4 capable of providing a reliable and simplistic means of securing adjacent vertebrae bodies or
5 interbody device during spinal fusion. Fixed, variable, and dynamic screw and plate combinations
6 are included.

7 It is a further object to provide a secure means of attaching a fixation plate to separated or
8 partially separated vertebral bodies by means of a threaded screw device which may continue to
9 rotate after firmly inserted through the plate, allowing the plate to be drawn tightly onto the bodies.

10 Installation and removal of the screws are only permissible through axial rotation of the screw, and
11 not axial (i.e., along the longitudinal axis) or transverse (i.e., in a plane perpendicular to the
12 longitudinal axis) loading.

13 Another object is to provide a system accommodating different screw designs, e.g., (a) screws
14 which remain at a fixed angle to the plate, (b) screws which are allowed to angulate or pivot relative
15 to the plate and (c) screws and an associated plate design that allows the screws to angulate and
16 traverse relative to the plate.

17 A plate system for immobilizing adjacent vertebral bodies in accordance with the present
18 invention includes a plate having at least one opening therein spaced to overlie the vertebrae bodies
19 to be immobilized. Each opening has an upper section with a preselected width w_1 for receiving the
20 head section of a cervical screw and a threaded lower section which may include a screw receiving
21 ring therein, has a width less than w_1 and defines at least a partial helical track through which the
22 threaded end of the screw may be threaded.

23 A bone screw for use with the plate has a cylindrical head section of one diameter, an
24 intermediate neck section of a second diameter and a depending thread section of a third diameter.
25 The threaded section of the screw has a pitch matching the pitch of the partial helical track in the
26 plate. The neck diameter of the screw has a smaller diameter than that of the head section or the
27 screw head with the threaded section of the screw being arranged so that once the screw is threaded
28 completely into the plate opening the screw may be rotated relative to the plate without causing any
29 axial movement between the screw and plate.

Brief Description of the Drawings

Fig. 1 is a top perspective view of a cervical plate adapted to receive screw receiving rings in the four outermost holes and a screw in the center slot in accordance with the invention;

Fig. 2 is a bottom perspective view of the plate of Fig. 1;

Fig. 3 is a top perspective view of an alternate embodiment of the plate for accommodating a slidable ring/screw in the center slot;

Fig. 4 is a top plan view of an alternate embodiment of a plate with two screw receiving slots on the left side, an opening on the lower right side for accommodating a ring receiving screw and a opening on the upper right for receiving a screw per se;

Figs. 5 and 6 are top and bottom perspective views, respectively, of a screw receiving ring adapted to be inserted into the ring receiving openings in the plate for allowing the screw to rotate relative to the plate without axial movement;

Fig. 7 is a bottom plan view of the plate of Fig. 1 illustrating the manner in which a screw receiving ring may be installed in an associated opening in the plate (top right);

Fig. 8 is a cross-sectional view taken along lines 8-8 of Fig. 7 illustrating the manner in which a press fit between the anti-rotation tabs on the ring and the respective receptacle pockets in the plate openings hold the ring in place and prevent it from rotating;

Fig. 9 is a top perspective view of the plate of Fig. 3 with a screw receiving ring installed in the center slot;

Fig. 10 is a front elevational view of a generic screw, e.g., fixed or variable angle, for use with the associated openings in the plate/rings;

Fig. 11 is a side elevational view partially broken away and in cross section of an assembly ring and screw.

Fig. 12 is a cross-sectional view of a fixed angle screw/plate/ring assembly;

Fig. 13 is a cross-sectional view of a variable angle screw/plate/ring assembly;

Fig. 14 is a top perspective view of the plate of Fig. 1 with fixed, variable and dynamic screws and associated rings in place;

Figs. 15-18 illustrate several views of an alternate embodiment of a screw having a separate head section with Figs. 15 and 16 showing the lower section of the screw, partially broken away and

1 in cross section in Fig. 16, and with Figs. 17 and 18 showing a plan and side view respectively of
2 the top disk section of the screw

3 Description of the Preferred Embodiment

4 Referring now to the drawings and particularly to Figs. 1 and 2, a cervical plate 10 has
5 openings 12 adapted to be located over two adjacent vertebral bodies (not shown), and an additional
6 opening in the form of a slot 14 adapted to span the distance between adjacent vertebral bodies.
7 Each of the circular openings have an upper section 16 with a pre-selected width w_1 (or diameter if
8 circular as is the case with the openings 12) for receiving the head of a screw to be described. The
9 openings further have lower sections 18a and 18b for the openings 12 and 14, respectively. The
10 lower sections 18a define an internal arc or spherical inner surface in cross-section which
11 accommodates a ring (to be described) and allows the ring to pivot or angulate relative to the plate
12 as will be explained.

13 The lower section 18b of the slotted opening 14 defines a partial helical track 14a thread on
14 each end through which a screw may be threaded as will be described. The w_2 of the slot 14 between
15 the helical end tracks is wider than the neck of the screw to be inserted into the track, but narrower
16 than the threaded shaft of the screw to be described in conjunction with Fig. 10. The width of the
17 slot allows the screw to travel along the slot and allow vertebral bodies to settle during fusion. The
18 partial helical tracks are adapted to accommodate one screw each. Diametrically opposing notches
19 16a (Fig. 2) are formed in the lower sections 16 of the openings 12 to receive fit anti-rotation tabs
20 on rings to be inserted into the lower sections of openings 16 as will be described.

21 A modified plate 20 is illustrated in Fig. 3 in which the central opening or slot 22 has a lower
22 section 24 which is arranged to receive one or possibly two screw receiving rings allowing the
23 ring/screw assembly to translate along the slot much like screws could translate along the slot 14 of
24 the plate 10 of Figs. 1 and 2.

25 Referring to Fig. 4 an alternative plate 26 is provided with an opening 12, the lower section
26 thereof being arranged to accommodate a screw receiving ring, two slotted openings 28 and a
27 circular opening 29, each of the latter having threaded lower sections arranged to receive a screw
28 directly, as will be described.

29 The preceding figures illustrate only basic plate variations capable of fusing only two

1 adjacent vertebrae, or a one level fusion. The plate could be extended to multiple levels to aid
2 multiple level fusion or reduced to only attach to one vertebrae body and overhang into the disk
3 space to buttress or stabilize an interbody device. Multiple variations are possible regarding screw
4 hole locations, ring locations, and slotted ring locations. For example, a three or four level plate may
5 contain two parallel slots rather than spherical holes at the screw locations in order to allow the
6 vertebrae bodies to settle during fusion.

7 Referring now to Figs. 5 and 6 (top and bottom views) a screw receiving ring 30 for insertion
8 into the lower sections of certain of the plate openings, i.e., 12, described previously, forms the lower
9 helical thread section 32 of the plate opening. It is to be noted that the term plate as used herein
10 encompasses a plate with one or more rings installed in the lower section of the associated openings
11 or a plate in which the lower sections of one or more openings are threaded directly to receive the
12 screws.

13 The ring is provided with top and bottom chamfers 33a and 33b, respectively. The chamfers
14 match corresponding chamfers merging with the neck of a screw as will be described in the
15 discussion of Fig. 10. It is to be noted that the threads 32' and chamfers 33a and 33b comparable to
16 the threads and chamfers (32, 33a and 33b) may be formed directly in the lower sections of the plate
17 openings, such as opening 29, for receiving a screw directly.

18 The upper peripheral surface 34 of the ring 30 matches the annular interior spherical surface
19 18a of the lower section of the plate openings designed to accommodate rings, e.g., openings 12, 22.
20 See Figs. 1 and 9. The cooperating spherical surfaces allow the ring to pivot in a circular manner
21 relative to the plate as is illustrated in Fig. 13. The ring 30 has radially protruding anti-rotation tabs
22 36 on the bottom end thereof as is illustrated in Figs. 5 and 6. These tabs are adapted to be inserted
23 into the cooperating receptacles or cavities 18c in the lower section of the ring accommodating
24 openings of the plate to prevent the rings from rotating in response to the rotation of a screw therein.
25 In addition, there is press or friction fit between the tabs 36 and the cavities 18c to maintain the rings
26 in place within the plate openings after installation. It is to be noted that the tabs do not prevent the
27 rings from pivoting within the plate openings as is illustrated in Fig. 13. It is to be noted that the
28 anti-rotation feature of the rings/plate openings can be accomplished in other ways, e.g., the tabs
29 could extend from the plate to the ring, a wedge could be inserted between the cooperating surfaces

1 of the ring and plate opening or friction forces between such surface may be sufficient to prevent ring
2 rotation.

3 The ring shown in Figs.5 and 6 may be inserted into an associated plate opening by first
4 positioning the top surface 35 (or bottom surface 37) perpendicular to the plate, as shown in the
5 upper left opening of the plate of Fig. 7, so that the anti-rotation tabs 36 rest within the transverse
6 notches 18c and so that one side of the ring extends through the center of the opening. The ring is
7 then rotated 90 degrees to rest relatively parallel to the plane of the plate. The openings on the left
8 side of the plate shown in Fig. 7 have rings installed in the lower sections thereof.

9 Fig. 8 is an enlarged view partially in cross-section taken along lines 8-8 of Fig. 7 illustrating
10 the initial installation step of installing a ring into the lower section of an opening 12. Fig. 9
11 illustrates the plate of Fig. 3 with a ring 30 installed in the lower section of the opening 22.

12 Referring now to Fig. 10 there is illustrated a screw 40 for use with a plate in which the lower
13 sections of the openings define threads in the wall of the plate, as is the case with the opening 29 of
14 Fig. 4 or the center slot of the plate of Fig. 1 or with a ring 30. The screw 40 includes a disk-shaped
15 head 40a having a diameter d_1 , an unthreaded neck 40b having a diameter d_2 , a threaded lower shaft
16 40c with an outside diameter d_3 . The threads may, for example, be self tapping fluted bone threads
17 with either single or double pitch.

18 The unthreaded neck 40b allows a fully seated screw, i.e., inserted into the plate (with
19 internal threads or with a ring) to continue to rotate without the threads thereof engaging the threads
20 in the plate or ring. Thus, the screw, once fully inserted, will not translate or move axially (along
21 the screw's longitudinal axis x-x) relative to the plate or ring during rotation. See Fig. 11.

22 The screw includes chamfers 40d and 40e which match the ring chamfers 33a and 33d,
23 respectively. The chamfers allow the screw, once installed, to rotate in the ring without moving
24 axially of the ring. Fig. 11 illustrates a screw 40 fully inserted into a ring 30. The upper chamfer
25 33a of the ring in addition to allowing the screw to rotate freely of the ring, once installed, acts as
26 a guide for starting the screw through the ring. It should be noted that the chamfers are not required
27 and could be replaced by a stepped relief between the screw head and the threads.

28 The diameter d_1 of the screw head relative to the width or diameter w_1 of the plate upper
29 section opening determines whether or not the screw is fixed, i.e., cannot pivot to any substantial

1 degree within the plate opening or is variable, i.e., allowed to pivot within the opening. Where d_1
2 is substantially equal (but slightly smaller) than w_1 (hereinafter $d_1 \cong w_1$), the screw can not pivot to
3 any substantial degree, i.e., the screw is classified herein as a fixed screw. Where $d_1 < w_1$ the screw
4 can pivot within the opening, i.e., the screw is classified herein as variable. The fixed angle screw
5 design with its upper cylindrical section (screw head) 40a (Fig. 10) having a diameter d_1 (~.222")
6 about equal to the diameter or width w_1 of the upper section 16 of the opening in the plate (~.224")
7 prevents any pivotal movement of the screw when completely inserted into the ring. The head
8 diameter d_1 of the variable screw would be further undersized (~.200") as to allow for a desired
9 variable angle relative to the plate's tangent direction (Fig. 13).

10 Fixed and variable screws, as classified herein, are illustrated in Figs. 12 and 13, respectively,
11 with the variable screw having a $d_1 < w_1$ being able to pivot relative to the plate 10 (Fig. 13) while
12 the fixed screw having a $d_1 \cong w_1$ is not able to pivot (Fig. 12). A dynamic screw like a variable
13 screw has a head diameter $d_1 \cong w_1$ or $d_1 < w_1$. The distinction is that a dynamic screw when
14 positioned within a slotted opening such as the opening 14 in Fig. 1 laterally along the slot, one
15 installed through the partial helical track 14a.

16 Examples of fixed, variable and dynamic screws, 42, 44 and 46, respectively, as installed in
17 a plate 10 (Figs. 1 and 2) is illustrated in Fig. 14. The fixed screw 42 cannot pivot while the variable
18 screw 44 can. The dynamic screw with a head section wherein $d_1 < w$ can not only pivot, but move
19 laterally along the slot 14.

20 It is noted that a plate with a single opening such as 29 of Fig. 4 can be used with a single
21 screw, the screw and the lower section of the plate opening having the chamfers, discussed
22 previously, to buttress a single vertebrae or interbody device. The chamfers prevent the screw from
23 backing out of the plate.

24 Figs. 15-18 illustrate an alternate screw arrangement, i.e., a two part screw comprising a
25 lower screw threaded section 50 and a locking top disk 52. Section 50 includes a neck 50a, which
26 serves the function previously described and a top threaded portion 50b on which the disk section
27 52 is threaded to complete the assembly. The locking top disk 52 may be rotated via the opposing
28 notches 52a independently after the screw is threaded into the threaded opening in the lower section
29 of the plate (with or without a ring) to firmly clamp and create a rigid fixation to the plate. The plate,

1 screw and ring (where used) is preferably made of titanium.

2 In summary, the invention comprises a cervical plate with openings having lower threaded
3 sections (at least on one end where the opening is a slot) incorporated directly in the plate or via an
4 installed ring and a fixed angle or variable angle screw. Both screws may serve as a transverse
5 sliding or dynamic screws when positioned inside of a slotted opening. The threads of the screws
6 are allowed to pass entirely through the plate (and ring where incorporated into the plate) by means
7 of axial rotation. A fully seated screw will not have interlocking threads with the plate and the user
8 may continue to rotate the screw to fully seat or pull the plate against the vertebrae bodies. The
9 chamfers on the plate/ring and adjacent the neck (top and bottom) of the screws will not allow the
10 screw to back out of the plate/ring by means of an axial or transverse load. This essentially locks
11 the screw to the plate without the need for a secondary locking mechanism. A fixed screw, that will
12 not rotate, may be held in a rigid position by a secondary locking mechanism incorporated into the
13 screw head as is illustrated in Figs. 15-18, if necessary.